BIO-MED DEVICES
IC-2A ADULT
INTENSIVE CARE VENTILATOR
INSTRUCTION MANUAL

CATALOG #8050A
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REV 122606

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CE
0086

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ADDENDUMS

MAGNETIC RESONANCE IMAGING ENVIRONMENT

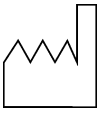
WARNING: ONLY AN IC-2A ORIGINALLY MANUFACTURED BY BIO-MED DEVICES FOR MRI USE OR RECEIVING AN MRI CONVERSION BY BIO-MED DEVICES IS TO BE USED IN AN MRI ENVIRONMENT. THESE UNITS WILL BE DESIGNATED BY AN MRI LABEL AND AN “M” AS A SUFFIX TO THE SERIAL NUMBER.

WHEN USING THE IC-2A/MRI VENTILATOR IN AN MRI ENVIRONMENT, THE FOLLOWING PRECAUTIONS MUST BE TAKEN:

- THE VENTILATOR MUST NOT BE PLACED INSIDE THE MRI BORE (SEE APPENDIX B).
- DO NOT USE ANY ACCESSORIES, INCLUDING OXYGEN AND AIR CYLINDERS, REGULATORS, MOUNTING BRACKETS AND SUPPORT STANDS, THAT ARE MADE OF ANY METAL THAT COULD BE ATTRACTED BY A MAGNET.

SYMBOL EXPLANATION

Attention, See Instructions for Use



Date of Manufacture

SN Serial Number

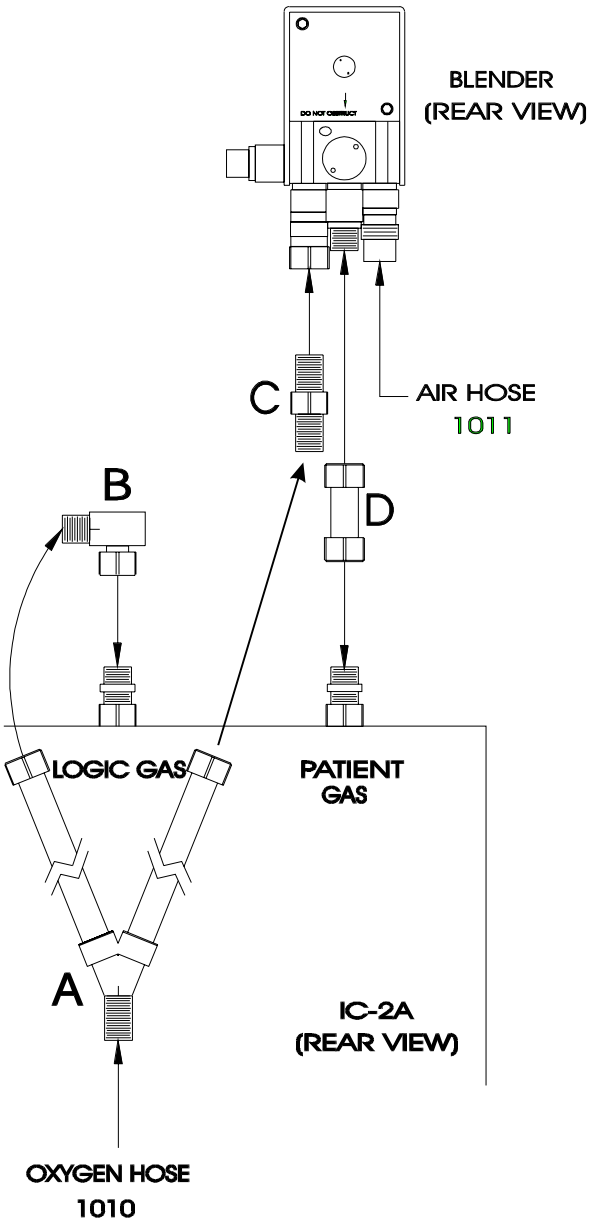
REF Catalog Number

CE
0086

The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.

IC-2A WITH TOP MOUNTED BLENDER

The following instructions explain how to make the connections between your IC-2A and blender using the Bio-Med Blender Hose Kit, catalog #2005IC.



1. Mount the blender to the IC-2A using the nut to nut coupler (D) – (blender primary outlet to IC-2A patient supply).

2. Connect the air supply hose (1011) to the air supply fitting on the blender.

3. Connect the elbow fitting (B) to the leg of the high pressure wye (A) and the other side of the elbow to the logic supply fitting on the IC-2A.

4. Using the coupler (C), connect the other leg of the high pressure wye to the O_2 supply fitting on the blender.

5. Connect the O_2 supply hose (1010) to the wye.

BLENDER SETUP INSTRUCTIONS WITH HEAVY DUTY STAND

Setup instructions for the IC-2A and optional blender using hose kit #2005ICHC

This hose kit is intended for use when cylinders are used with the IC-2A complete package, Catalog #8001AMBC.

Prior to mounting the pole to the base, slip the cylinder brackets over the end of the pole. Put the open bracket on first and then the one with the bars across the rings. The bars should be down (closest to the end of the pole). Install the pole to the base. Secure the pole to the base with the washer and nut.

Mount the blender bracket **(pins down)** approximately 12" from the top of the pole.

Place the blender in the bracket.

Place the IC-2A in the top tilt bracket.

Install the oxygen cylinder with regulator in the cylinder bracket to the right and with the supply output fitting facing forward. If using Bio-Med's Deluxe Regulator, then the 50 PSI Out fitting should face forward.

Install the air cylinder with regulator in the cylinder bracket to the left and with the supply output fitting facing to the rear. If using Bio-Med's Deluxe Regulator, then the 50 psi out fitting should face forward.

Use the elbows (3) in the following locations. Face the threads as indicated:

Logic supply input on the IC-2A- face threads to the rear
Patient supply input on the IC-2A- face threads to the rear
Blender output- face threads to outside of blender air fitting

The high pressure wye is to be used to split your oxygen source before the blender so the short leg goes to the blender input and the long leg goes to the IC-2A logic input. Connect one end of a 2' oxygen supply hose to the input of this wye and the other end to the output fitting on the oxygen cylinder regulator.

Connect one end of the 2' air supply hose to the output fitting on the air cylinder regulator and the other end to the blender air input.

Connect the remaining 2' supply hose from the elbow on the blender output to the IC-2A patient supply input.

If using Bio-Med's Deluxe Regulators, use the 10' air & oxygen hoses and connect the 50 PSI Input fittings to corresponding wall sources, if desired.

Setup instructions for the IC-2A and optional blender using hose kit #2005ICH

This hose kit is intended for use when cylinders are NOT used.

Mount the blender bracket **(pins down)** approximately 12" from the top of the pole.

Place the blender in the bracket.

Place the IC-2A in the top tilt bracket.

Use the elbows (3) in the following locations. Face the threads to the rear.

Logic supply input on the IC-2A.
Patient supply input on the IC-2A.
Blender output.

The enclosed high pressure wye is to be used to split the oxygen source before the blender so one leg goes to the blender input and the other to the IC-2A logic input.

Connect the 10' oxygen supply hose to the input of the wye.

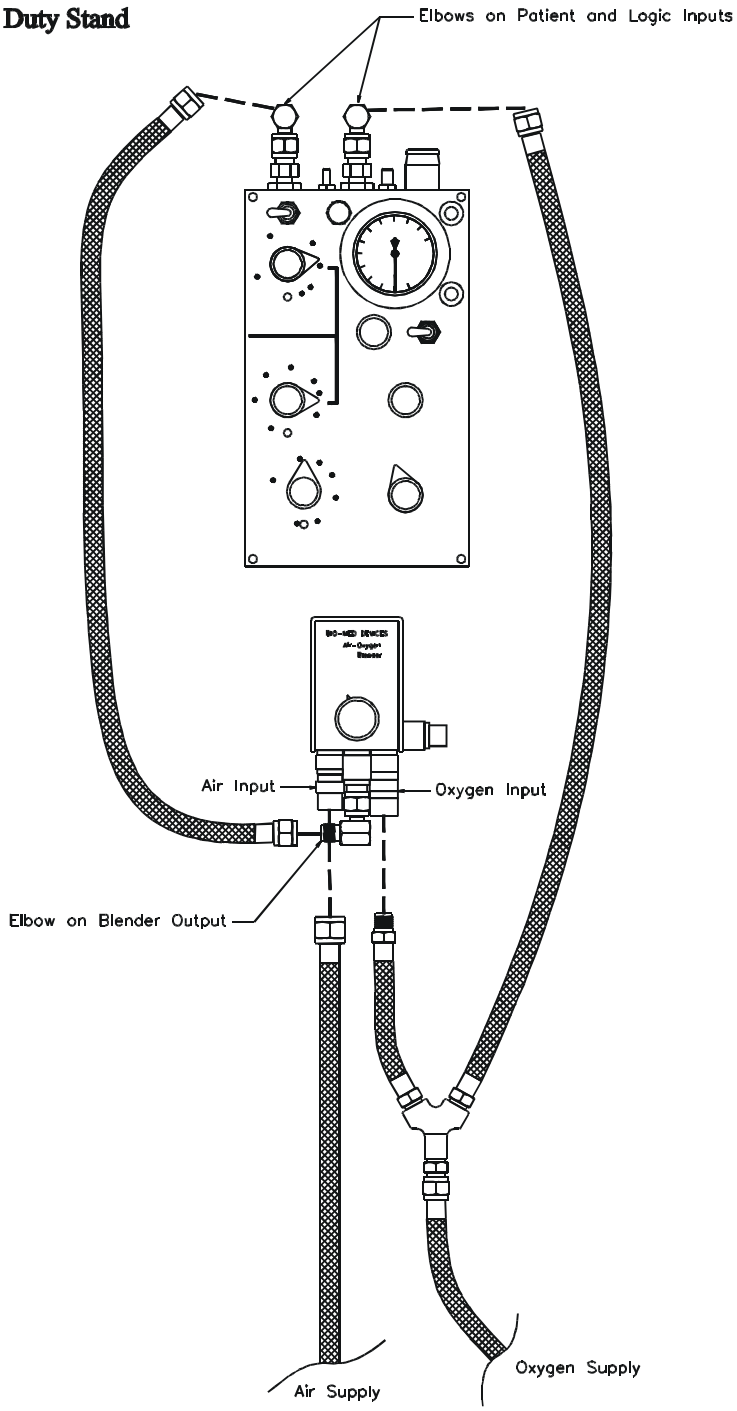
Connect the short hose leg of the wye to the blender oxygen input .

Connect the long hose leg of the wye to the elbow on the IC-2A logic supply input.

Connect the 10' air supply hose to the blender air input.

Connect one end of the 2' supply hose to the elbow on the blender output and the other end to the elbow on the IC-2A patient supply input.

Blender to IC-2A hose connections when mounted to a BMD Heavy Duty Stand



UNPACKING

When received, the instrument should be immediately unpacked and checked to see that all component parts have been received, and that there is no apparent damage.

If the IC-2A was shipped directly to you and damage due to shipment is found, notify the carrier at once. Only you, the consignee, can make a claim against the carrier for damage in shipment.

If you received the equipment from a BMD dealer, return it to the dealer for adjustment.

In addition to the ventilator, the following items are shipped standard as part of the IC-2A equipment. Check to assure that all items have been received.

For IC-2A, Catalog #8001A or 8001AM

QTY	CAT. #	DESCRIPTION
1	CCAP005	CAP ON IC-2A PATIENT OUTLET
1	2013	MOUNTING BRACKET
1	8005	HIGH PRESSURE WYE
2	PFIT143	SUPPLY ELBOW ADAPTERS
1	1010	10' HIGH PRESSURE O_2 SUPPLY HOSE
1	1020	ADULT TEST LUNG
2	8002A	DISPOSABLE PATIENT CIRCUIT
1	8050A	IC-2A INSTRUCTION MANUAL
1	------	WARRANTY CARD

For IC-2A Complete Package, Catalog #8001AMBC

QTY	CAT. #	DESCRIPTION
1	8001AM	IC-2A MRI VENTILATOR
1	CCAP005	CLEAR CAP ON IC-2A PATIENT OUTLET
1	2001M	HIGH/LOW FLOW MRI BLENDER
1	1060-5HM	5-LEGGED HEAVY DUTY MRI STAND
1	PFIT143	SUPPLY ELBOW ADAPTERS
1	1020	ADULT TEST LUNG
2	8002A	DISPOSABLE PATIENT CIRCUIT
1	8050A	IC-2A INSTRUCTION MANUAL
1	2120	BLENDER INSTRUCTION MANUAL
1	1005M	MRI DELUXE REGULATOR FOR O_2 E-CYLINDER
1	1006M	MRI DELUXE REGULATOR FOR AIR E-CYLINDER
1	1061M	E-CYLINDER BRACKET SET FOR HEAVY DUTY STAND

2	MLAB024	WARRANTY CARD
1	2005ICHC	HOSE KIT FOR 8001AMBC (see below)

2005ICHC HOSE KIT INCLUDES THE FOLLOWING:

QTY	CAT. #	DESCRIPTION
2	PFIT143	SUPPLY ELBOW ADAPTERS
1	8005BH	HIGH PRESSURE WYE FOR BLENDER ON STAND
2	1010-2	2' OXYGEN SUPPLY HOSE
1	1010	10’ OXYGEN SUPPLY HOSE
1	1011-2	2’ AIR SUPPLY HOSE
1	1011	10’ AIR SUPPLY HOSE
1	2013BH	BLENDER BRACKET FOR HEAVY DUTY STAND

WARRANTY

The IC-2A Ventilator is warranted to be free from defects in workmanship and material for one (1) year from the date of purchase. To insure its performance is maintained, any repair during this warranty period must be performed by BMD.

The warranty does not apply to the patient circuit and hoses supplied with the instrument. Nor does the warranty cover abuse or misuse of the instrument, or damage due to unauthorized servicing.

If service is required, the instrument must be properly packed and shipped pre-paid, directly or through your dealer, to:

BIO-MED DEVICES, INC.
61 SOUNDVIEW ROAD
GUILFORD, CT 06437
(203) 458-0202

An explanation of the problem should accompany the equipment. Please include your name and telephone number with the paperwork.

There is no oral or implied warranty of the instrument's fitness for a particular purpose other than its intended use.

WARNINGS

Clean, dry, regulated gas supplies at 50 ±5 psi (345 ±34.5 kPa) must be used at all times or malfunction may result. Note carefully that the logic gas supply should be 100% oxygen at all times to give the greatest accuracy of the control settings and to assure the most trouble-free operation. The supply connected to the patient supply connector may be either: 100% oxygen, air from a dry gas medical air compressor system or a blended mixture of air and oxygen.

A TWO-WAY SAFETY RELIEF VALVE is installed internally. This valve opens when pressure in the hose delivering gas to the patient rises above 120 cmH_2O ± 10 cmH_2O or falls below -4 cmH_2O. Its purpose is to limit maximum circuit pressure and to allow patient inspiration in the unlikely event of failure of the gas supply. It must be maintained and its screen side clear and unobstructed. It is meant to allow spontaneous breathing for a short time only until the operator can respond to the disconnect alarm and rectify the supply malfunction. In such a situation, its use in a contaminated environment could be hazardous.

Do not re-use disposable breathing circuits.

Do not use in a MRI room unless the IC-2A has been built by Bio-Med Devices for such an environment. This will be indicated by a MRI plaque on the top of the unit and a “M” at the end of the serial NUMBER.

If the ventilator is to be used unattended or without remote monitoring, a high/low pressure alarm must be used at all times with the user within visual and/or audible range of this alarm. Recommended monitors for this purpose are Bio-Med Devices’ M-1 or M-10.

Any HUMIDIFIER used with the IC-2A must be a "flow-through" type having a low pressure drop. Use of a humidifier with a "bubbler" tube or pressure jet will render the SAFETY RELIEF VALVE ineffective.

CAUTIONS

The IC-2A ventilator is intended for use by qualified clinical personnel only. This instruction manual should be read in its entirety before using the equipment.

Always test the IC-2A each time before connecting to the patient.

As noted later in the text of this manual, the IC-2A time cycle settings are affected by large changes in barometric pressure, flow rates, and gas composition. They are repeatable, however, within 5% under constant conditions. As with any ventilator, periodic blood gas studies should be made to insure proper levels of ventilation.

A one-way valve is installed internally in the patient manifold. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm h_2o. Its purpose is to allow patient inspiration in the event of gas supply failure. It is meant to allow spontaneous breathing for a short time only until the operator can respond to the disconnect alarm and rectify the supply malfunction.

A patient filter should always be used with the IC-2A to prevent cross contamination and protect the patient.

Always turn on the IC-2A before attaching to patient to avoid erroneous breaths.

Whenever the IC-2A is turned off, disconnect the patient before turning the ventilator back on in order to avoid erroneous breaths.

Antistatic or electrically conductive hoses or tubing should not be used.

I. GENERAL

A. INTENDED USE

The Model IC-2A Ventilator is for respiratory support of adult patients both in hospital and during transport. It may be used either volume or pressure limited and with a wide range or I\E ratios less than or greater that 1:1.

WARNING: Do not use in a MRI room unless the IC-2A has been built by Bio-Med Devices for such an environment. This will be indicated by a MRI plaque on the top of the unit and a “M” at the end of the serial NUMBER.

B. MODES OF OPERATION

It is a pulsatile flow Ventilator which may be used in any of the following operating modes:

- Time cycled, either volume or pressure limited, with or without Positive End Expiratory Pressure (PEEP).
- Intermittent Positive Pressure Ventilation (IPPV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure (CPAP).
- Manual

C. FEATURES

Portable: Compact and light weight. May be hand carried or attached to stand; used without interruption during transportation; compatible with masks, endotracheal tubes and tracheostomy tubes.

Gas Powered: Portable pressurized tank or wall outlet, providing 50 psi oxygen or air.

Operable in Hazardous Areas: Non-electric, no shock hazard, case constantly self-purged.

High Reliability: Controlled by miniature pneumatic logic elements; with negligible frictional wear.

Very low compliance.

Readily usable with standard accessories: humidifier, oxygen blender, oxygen analyzer, pressure alarms, and patient circuit.

D. PERFORMANCE CHARACTERISTICS

Direct control is provided for inspiratory and expiratory times, flow rate, and maximum pressure and PEEP or CPAP levels within the patient circuit.

Oxygen concentration: variable, 21% to 100% with external blender.

Respiratory rate: variable, $1^1/_3$ to 66 breaths/min.

Tidal volume: variable, 0 to over 3000 ml.

I/E ratio: variable.

Respiratory and I/E ratio are determined by INSP. TIME and EXP. TIME control settings. These settings are repeatable within 5%.[1] For greater accuracy of settings and external monitoring device may be used.

Oxygen concentration is varied by the use of an external accessory blender or premixed gas supply. Care should be taken to select a blender capable of maintaining constant supply pressure over the full range of flow rates that the IC-2A provides. As with all ventilation systems, the O_2 concentration should be tested periodically with an oxygen analyzer.

The tidal volume, when the ventilator is operated in a volume limited mode, is the product of flow rate (converted to ml/sec) and inspiratory time:

TIDAL VOLUME (ml) = FLOW RATE (ml/sec) X INSPIRATORY TIME (sec)

NOTE: Flow rate is not Minute Volume
MINUTE VOLUME = TIDAL VOLUME X RESPIRATORY RATE

It should be noted that the MAX PRESSURE and PEEP/CPAP control settings are affected slightly by flow. When flow is increased, the pressure levels set by these controls will increase somewhat. These changes may be noted on the pressure gauge and the settings readjusted.

[1] *At elevations above sea level, the intervals set by the INSP. TIME and EXP. TIME controls are increased due to lower barometric pressure. The difference is about 2.5% per 1000' of elevation. With an air supply connected to the POWER OXYGEN inlet fitting, the time intervals are about 10% less than with pure oxygen connected*.

II. DESCRIPTION

A. PRINCIPLES OF OPERATION

1. IPPV

With the CYCLE/CPAP-MANUAL selector set in cycle and NORMAL/SIMV selector set in normal, the IC-2A acts as a controller or assist/controller. A pilot valve operated by the timing signal from the fluid logic opens for a preset length of time (Insp. Time) allowing gas to flow at some rate established by the flow rate control. During this time the exhalation valve is pressurized, closing the exhalation port and thus insuring that all gas is directed to the patient. The gas supply is a high pressure source and since the pressure reached in the patient is relatively low, the flow rate remains constant, independent of changes in patient pressure. The ventilator is a constant flow generator.

a. Volume Limited

The pressure developed in the system depends on the total compliance and the volume of gas delivered. If the adjustable pressure limit is set higher than the pressure that is reached, then no gas is dumped to atmosphere and the ventilator is volume limited. In this mode the tidal volume (V_t) is the product of inspiratory time and flow rate.

$$V_t = T_I \times V_I$$

In this mode the pressure limit is normally set 5-10 cmH_2O above the pressure attained. It then acts as an upper level failsafe. If patient resistance or compliance cause a significant increase in pressure, the pressure will be limited at the preset level. When this occurs the ventilator is no longer volume limited since some gas is dumped to atmosphere and therefore the tidal volume is unknown.

b. Pressure Limited

Whenever the pressure reached within the patient circuit is equal to the maximum pressure limit established using the maximum pressure control on the rear panel, the excess gas is dumped to atmosphere and the unit is operating in a pressure-limited mode. The ventilator may be used continuously in the pressure limited mode by setting the maximum pressure and adjusting the inspiratory time and flow rate to give a large enough volume of gas per breath to insure that the preset pressure level is reached on each cycle. When the pressure limit is reached, it is held until the end of inspiration thus producing a "plateau" type pressure waveform.

The lowest rate attainable in the IPPV mode is established by the backup timer at 6 breaths/min.

2. Synchronized Intermittent Mandatory Ventilation (SIMV)

The IC-2A provides a unique triggered demand-flow system for the addition of a constant flow source. It obviates the need of check valve, flowmeter,

bag, etc. The expiratory time is set in the IMV range allowing the patient one or more spontaneous breaths between the machine assisted breaths. It should be noted that in the SIMV mode it is essential that the inspiratory effort control be set so that the patient can trigger the machine at all times. When the NORMAL/SIMV selector is set in the SIMV position it will be observed that while the ventilator cycles with each inspiratory effort, the pressure builds up in the patient circuit only after the end of the expiratory time. This is achieved by pressurizing the exhalation valve only after the patient triggered breath at the end of the expiratory time (assisted breath). At the end of the expiratory time the machine waits for the next inspiratory effort and therefore when the assisted breath is provided it is synchronized to the patient's breathing effort. In the SIMV mode, in the event no patient inspiratory effort is sensed for a period of ten seconds, a "backup timer" will provide a "backup breath." Every time an inspiratory effort is sensed, whether for a spontaneous or an assisted breath, the backup timer is reset. The interval between assisted breaths may still be set to the maximum expiratory time of at least 45 seconds.

Each time the machine is cycled it provides gas flow to the patient even when the exhalation valve is not pressurized. If the inspiratory time and flow rate are set in a way that provides more gas than needed by the patient, the excess passed to the atmosphere. Should the patient require more gas during a spontaneous breath than is provided, and if a negative pressure is still being generated (following the termination of the inspiratory period), another inspiratory period (and as many more as necessary) will be initiated, thus providing as much gas as required. The patient may exhale at any time during spontaneous breathing since the exhalation valve is not pressurized. It is, however, desirable to set the flow rate and inspiratory time to give a tidal volume as close to the spontaneous tidal volume as possible. With this triggered demand-flow system, it is only necessary to trigger the unit initially. The IC-2A then provides a bolus of gas equal to the inspiratory time multiplied by the flow rate. Unlike other systems it is not necessary to maintain a constant negative pressure of several cmH_2O during each spontaneous breath. This eliminates the oscillations observed in other systems at low flow rates and makes possible the use of a normal bubble type humidifier with the bubbler in place. Note that during the spontaneous breaths, even though the exhalation valve is not pressurized, there may be a buildup of 3-5 cmH_2O pressure depending on flow rate set. This is due to slight resistance of the exhalation valve at high flow rates.

3. Positive End Expiratory Pressure (PEEP)

The PEEP/CPAP control applies a constant pressure to the exhalation valve which may be adjusted to give a pressure in the patient circuit from 0 to 25 cmH_2O. The PEEP/CPAP control is operative in all modes of operation. The inspiratory effort control may be set to compensate for the PEEP/CPAP pressure level in the patient circuit. Whenever the PEEP/CPAP level is changed, the inspiratory effort control should be readjusted.

4. Continuous Positive Airway Pressure (CPAP)

When the CYCLE/CPAP selector switch is placed in the CPAP-MANUAL position the function of the IC-2A is very similar to the SIMV mode. In the

CPAP mode, an inspiratory effort triggers the flow of a volume of gas equal to inspiratory time X flow rate. However, in this mode the high pressure is not applied intermittently to the exhalation valve. Only the PEEP/CPAP control is operative. The PEEP/CPAP control may be turned fully clockwise thus applying zero pressure to the exhalation valve. In this way the ventilator may be used to administer, on demand, gas of a preset oxygen concentration at ambient pressure. In both the SIMV and CPAP modes there may be a momentary fluctuation of a few cmH_2O pressure depending on the flow rate, inspiratory time, system compliance and gauge response.

Note that in this mode, the expiratory time should be turned to maximum (fully clockwise) and the NORMAL/SIMV selector should be in the SIMV position. This will prevent false cycling and help to reduce gas consumption. It is also advisable, for added safety, the maximum pressure control be turned off (fully clockwise) when using the CPAP mode.

5. Manual Mode

The manual control can be used for hyperventilating before suctioning, sighing the patient or synchronizing with chest compressions for cardiopulmonary resuscitation.

The manual button is inoperative until the CYCLE/CPAP-MANUAL selector is switched to the CPAP-MANUAL position. The inspiration time is set with the inspiratory time control. The manual button should be depressed long enough on each cycle to set the inspiratory timer and then released. The inspiratory period will then last as long as the time set with the inspiratory time control. The tidal volume is then equal to the inspiratory time X flow rate (volume limited).

If the manual button is held in for a time greater than the preset inspiratory time, then inspiration will last during the entire time that the manual button is depressed. In this case the volume delivered is unknown. The pressure gauge may be observed as an indicator of degree or ventilation. By using the PEEP/CPAP control it is possible to ventilate manually with PEEP. The MAX. PRESSURE control may also be used in manual mode to pressure limit each breath.

B. CONTROLS, INDICATORS AND CONNECTIONS

1. Controls

a. CYCLE/CPAP-MANUAL Switch

Selects non-cycling (CPAP) or time-cycled (cycle) modes or operation.

b. Inspiratory Time

Sets inspiratory time in time cycled modes. Calibrated from 0.4 to 2.0 sec.

c. Expiratory Time

Sets expiratory time in time-cycle modes. Calibrated from 0.5 to 4

seconds (may be set to 45 seconds or more in IMV range).

d. Flow rate
Sets inspiratory flow rate. Calibrated from 0 to 75 LPM.

e. Inspiratory Effort
Adjusts the patient trigger sensitivity.

f. PEEP/CPAP
Sets PEEP level when cycle selector switch is in the CYCLE position or CPAP level when switch is set to CPAP.

g. NORMAL/SIMV Switch
Selects between normal time cycled mode and SIMV mode.

h. Off/On Switch
Controls main power to the fluid logic.

i. Manual Button
Provides manually controlled inspirations.

j. Maximum Pressure (Rear Panel)
Sets the upper pressure limit of each cycle.

2. Indicators

a. Pressure Gauge
Indicates proximal airway pressure. Calibrated from -20 to +120 cmH_2O.

b. Cycle Indicator
Indicates any time cycled inspiratory period.

c. Demand Indicator
Indicates any cycle initiated by patient breathing effort or backup timer.

3. Connections

a. Logic Power Supply (100% O_2)
A DISS oxygen fitting for connection to source of clean, dry, 50 ±5 psi (345 ±34.5 kPa) oxygen, to power logic.

b. Patient Gas Supply
DISS oxygen fitting for connection to source of clean, dry, 50 ±5 psi (345 ±34.5 kPa) supply of patient breathing gas mixture, e.g., from a blender.

c. Patient Hose Connection
22mm connector (inside 15mm) for attaching main patient hose.

d. Exhalation Valve Connector
Powers the exhalation valve.

e. Pressure Gauge
Connects to pressure gauge line "T" adapter to give proximal airway

pressure.

C. SPECIFICATIONS

Gas Supply	
Logic Oxygen:	Clean, dry, medical grade 50 ±5 psi (345 ±34.5 kPa) 100% oxygen.
Patient Supply:	Clean, dry, oil free 50 ±5 psi (345 ±34.5 kPa) patient breathing gas mixture.
Inspiratory Time:	Calibrated[2] from 0.5 to 4 seconds (variable to 45 seconds or more, uncalibrated, in the IMV range).
Flow rate:	Calibrated from 0 to 75 LPM.
Maximum Pressure Setting:	Variable from 0 to 120 ±20 cmH_2O. This is dependent upon the type of exhalation valve used. The IC-2A is calibrated using the Bio-Med Devices disposable patient circuit and exhalation valve, Part #8002A.
Pressure Gauge:	-10 to +120 cmH_2O; ±3% full-scale accuracy.
Failsafe Two-Way Relief Valve:	(Installed internally) opens at pressures above 120 ±20 cmH_2O or below -4 ±1 cmH_2O.
PEEP/CPAP Range:	Variable from 0 to 25 ±5 cmH_2O.
Logic Gas Consumption:	Approximately 12 LPM. Varies with control settings. Higher pressure increases consumption.
Weight:	4.1 kg (9 lbs.)
Physical Dimensions:	8.57 X 15.56 X 26.04 cm (3-1/8 x 6-1/8 x 10-1/4 in.)
Storage Temperature:	32° to 122°F (0°to 50°C)
Operating Temperature:	14° to 122°F (-10°to 50°C)

[2] *INSP. TIME and EXP. TIME control settings are calibrated at sea level and 20 degrees Celsius, using USP oxygen. Large changes of barometric pressure or altitude changes, or use of diluted oxygen will affect time calibration. Time settings are repeatable within 5%.*

III. INSTALLATION CONSIDERATIONS

A. EQUIPMENT REQUIRED

All equipment required for use of the IC-2A has been supplied with the instrument, except for the gas supply. No special tools are needed.

It will be convenient to have available a test lung, BMD Part #1020, when setting the ventilator parameters, before connecting to a patient.

B. SUPPLY GAS

The supply gas is normally a pressurized tank(s) or wall source of medical or therapy grade oxygen and/or air. The pressurized tanks should be fitted with regulators adjusted to 50 ±5 psi (345 ±34.5 kPa).

NO FLOW RESTRICTING DEVICE (e.g. FLOWMETER, THROTTLING VALVE) SHOULD BE PLACED IN THE SUPPLY LINE. A flow-restricting device interferes with the operation of the pneumatic logic and may render the time-cycling inoperative.

The IC-2A will operate with a supply pressure outside of the 50 ±5 psi (345 ±34.5 kPa) range, but accuracy of settings may be impaired. IN NO CASE SHOULD A SUPPLY PRESSURE LESS THAN 35 PSI (242 kPa) OR OVER 80 PSI (552 kPa) BE CONNECTED TO THE IC-2A AS IT WILL CAUSE MALFUNCTION OF THE VENTILATOR.

C. MOUNTING BRACKET

The supplied mounting bracket may be installed on any column up to 1.5" in diameter.

D. ANCILLARY EQUIPMENT

Other standard equipment that may be used with the IC-2A at the option of the user includes:

Oxygen Blender--any oxygen blender that provides sufficient flow rates at constant pressure may be used. BMD recommends use of the BIO-MED High Flow Blender, catalog #2001or #2002, with supply disconnect alarms. It should be connected to the "patient gas" connection.

Humidifier--any adult intensive care humidifier intended for use with a ventilator (such as the Fisher & Paykel available from Bio-Med Devices) may be used. It should be connected in line in the main patient hose. Due to the unique triggered demand flow system of the IC-2A, a bubble tower, if present in the humidifier used, may be left in place without adversely affecting the operation of the IC-2A.

Pressure Alarms--a high/low pressure alarm (such as the Bio-Med Devices M-10 or

M-1) may be connected to the pressure gauge line or main patient hose. IT MUST ALWAYS BE USED WHENEVER THE IC-2A IS USED UNATTENDED.

Rate-I/E Ratio Monitor--(such as the Bio-Med Devices M-10) may be connected if desired, to simplify use of the ventilator by supplying readout of rate and I/E ratio. It should be connected in the same way as the high/low pressure alarm.

Spirometer--any spirometer may be used to verify the tidal volume administered by the IC-2A. NO DEVICE SHOULD EVER BE CONNECTED TO THE EXHALATION VALVE LINE OR MALFUNCTION MAY RESULT.

IV. SET UP

CAUTION: Antistatic or electrically conductive hoses or tubing should not be used.

A. CONNECTION OF GAS SUPPLY

1. Connect a 50 psi (345 kPa) oxygen source to the logic power gas supply connector. Only 100% oxygen should be used for proper operation.

2. Connect the patient gas supply to the DISS fitting labeled "patient gas supply." This may be from the output of a blender or any pre-blended gas mixture of the desired oxygen concentration. The oxygen concentration delivered to the patient is the same as the oxygen concentration supplied to the ventilator in the patient gas fitting.

   It is essential that:

   THE SUPPLIES ARE REGULATED 50 PSI (345 kPa) SOURCES WITHOUT FLOW RESTRICTING DEVICES (E.G., FLOWMETER, NEEDLE VALVE, ETC.);

   HOSE FITTINGS SHOULD BE HAND TIGHTENED TO AVOID DAMAGE TO FITTINGS;

   THE GAS SUPPLY SHOULD BE CLEAN AND DRY.

B. CONNECTION OF PATIENT CIRCUIT

1. Connect the corrugated humidifier hose to the main patient output fitting. Connect the other end to the input port of the humidifier.

2. Connect the main patient hose (corrugated tube) to the output connector of the humidifier.

3. Attach the exhalation valve line to the exhalation valve fitting.

4. Connect the proximal airway pressure line to the pressure gauge fitting.

5. Attach patient port of exhalation valve to a test lung, BMD Part #1020. After selecting desired operating parameters observe proper functioning before attaching to the patient.

CAUTION: Do not re-use disposable breathing circuits.

Note:

Any intensive care ventilator circuit can be used with the IC-2A including a configuration utilizing both inspiratory and expiratory hoses. Any exhalation valve may be used. It should be noted that the IC-2A is supplied with the Bio-Med Devices patient circuit, catalog #8002A. The maximum pressure limit and maximum PEEP pressure are calibrated using this exhalation valve. If another valve is used there may be a difference in the maximum pressure limit and maximum PEEP pressure attainable, depending on the area ratios of the exhalation valve used.

V. SELECTION OF VENTILATION PARAMETERS AND ADJUSTMENT OF CONTROLS

A. INTERMITTENT POSITIVE PRESSURE VENTILATION (IPPV) WITH OR WITHOUT PEEP

Determine and note patient requirements for respiratory rate, I/E ratio and tidal volume. Refer to Table I to find inspiratory time (T_I) and expiratory time (T_E). Obtain the correct flow rate setting for the desired title volume at the set inspiratory time, from Table II.

Step 1- set ON/OFF selector to ON.

Step 2- set CYCLE/CPAP-MANUAL switch to cycle position.

Step 3- set NORMAL/SIMV switch to normal position.

Step 4- set maximum pressure control fully counterclockwise (maximum), PEEP/CPAP control fully clockwise (zero).

Step 5- adjust insp. time and exp. time controls to required settings.

Step 6- set flow rate control to proper position to give desired tidal volume according to Table II.

Step 7- set desired oxygen concentration with blender control.

Example:

Prescribed parameters:
Tidal Volume = 500 ml
Respiratory Rate = 20
I/E Ratio = 1.2
From Table I:
Insp. Time = 1.0 sec.
Expiratory Time = 2.0 sec.
From Table II:
Flow rate = 30 LPM (0.5 L/sec.)
[Tidal volume (liters) = flow rate (L/sec) X Insp. Time (sec.)]

Step 8- ATTACH TEST LUNG TO PATIENT PORT AND OBSERVE PROPER CYCLING.

Step 9- connect to patient.

Step 10- set inspiratory effort control for proper patient triggering.

Step 11- volume-limited or pressure limited operation is established as follows:

a) For volume limited operation - set the MAX. PRESSURE control fully

counterclockwise.

With patient airway connected to patient port observe and note maximum pressure during cycle.

Detach patient airway from WYE and block patient port.

Adjust MAX. PRESSURE control to a level 5 to 10 cmH_2O above that reached with patient connected.

Re-connect the patient airway to the WYE.

The IC-2A will now be limited to the tidal volume set, but maximum pressure will be limited in the event of changes in resistance or compliance.

b) For pressure-limited operation:

Adjust MAX. PRESSURE control until the desired pressure limit is attained during inspiration. Note that the MAX. PRESSURE level is somewhat affected by the flow rate. It should be set with the particular flow rate used.

The IC-2A will now be limited to the pressure set. When operating in this mode, the exact Tidal Volume is unknown, since gas is vented to the atmosphere through the exhalation valve as soon as the present pressure limit is reached during each inspiration.

Step 12- If PEEP is to be used, set the desired level using the PEEP/CPAP control.
Adjust control until the pressure gauge indicates the desired level during the expiratory time. Note that the PEEP level is somewhat sensitive to flow rate. The PEEP control should be set with the flow rate used. When using PEEP, the inspiratory effort control should be reset to compensate for each PEEP level used.

Note:
During IPPV an assist control breath will cause response of both the cycle and demand indicators. A control cycle will activate only the cycle indicator.

B. SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV)

Step 1- NORMAL/SIMV selector is set to SIMV position.

Step 2- set inspiratory effort control for proper patient triggering.

The volume of gas delivered during spontaneous breaths, equal to insp. time X flow rate, should be as close as possible to the patient's tidal volume. However, if it is set too high the excess gas not breathed by the patient is vented to atmosphere through the exhalation valve. If it is too low and the patient requires more gas, another bolus of gas will automatically be delivered to the patient as long as the

inspiratory effort sensor detects a negative pressure.

Step 3- set PEEP level, making certain to readjust the inspiratory effort control to compensate for PEEP.

Note:
In the SIMV mode it is unnecessary to add an external constant flow source due to the triggered demand flow system. It is necessary, however, that the inspiratory effort control be properly adjusted at all times to assure proper operation.

Step 4- observe assisted breath following termination of expiratory time. Adjust tidal volume equal to inspiratory time X flow rate to proper level.

Note:
In the SIMV mode, in the event no patient inspiratory effort is sensed for a period of ten seconds, a "backup timer" will provide a "backup breath." Every time an inspiratory effort is sensed, whether for a spontaneous or an assisted breath, the backup timer is reset.
The interval between assisted breaths may still be set to the maximum expiratory time of at least 45 seconds.

In SIMV, the demand indicator alone will show spontaneous breaths, while both demand and cycle indicators together indicate an assisted breath or a backup breath.

C. CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

NOTE:
WHENEVER THE IC-2A IS TURNED OFF, DISCONNECT THE PATIENT BEFORE TURNING THE VENTILATOR BACK ON, IN ORDER TO AVOID ERRONEOUS BREATHS.

THE MAXIMUM PRESSURE CONTROL MUST BE TURNED OFF (FULLY CLOCKWISE) IN THE CPAP MODE.

Step 1- set PEEP/CPAP control fully clockwise (zero).

Step 2- set CYCLE/CPAP-MANUAL switch to CPAP-MANUAL position.

Step 3- turn expiratory time control fully clockwise to maximum.

Step 4- set NORMAL/SIMV switch to SIMV.

Step 5- adjust inspiratory time and flow rate to give administered gas volume sufficient to meet patient demand.

Step 6- connect to test lung.

Step 7- set desired CPAP level using the PEEP/CPAP control.

Step 8- adjust inspiratory effort for pre-set CPAP level, for proper patient triggering.

NOTE THAT IT IS ESSENTIAL WITH THE TRIGGERED DEMAND FLOW OF THE IC-2A, THAT THE INSPIRATORY EFFORT BE PROPERLY ADJUSTED TO ASSURE THAT THE PATIENT CAN OBTAIN GAS.

As in the SIMV mode, no external constant flow source is necessary.

Step 9- connect to patient and observe pressure gauge. Adjust inspiratory time and/or flow rate to assure that sufficient gas is provided and that the CPAP level is maintained.

In CPAP, only the demand indicator will be activated.

D. MANUAL CYCLING

Step 1- set CYCLE/CPAP-MANUAL selector to CPAP-MANUAL position.

Step 2- set NORMAL/SIMV selector to SIMV. Set expiratory time to maximum.

Step 3- set desired inspiratory flow rate and inspiratory time.

Step 4- set maximum pressure level (rear panel control) by occluding patient port, depressing manual control and adjusting maximum pressure.

Step 5- adjust PEEP level in manner similar to maximum pressure, if it is desired to have PEEP during manual cycles.

Step 6- ventilate test lung by depressing manual button and observing pressure gauge for proper operation.

Step 7- connect to patient and ventilate by depressing manual button long enough on each cycle to set the inspiratory timer. If the manual button is held in longer than the preset inspiratory time, then inspiration will continue during the entire time that the manual button is depressed. Observe chest excursion and pressure gauge for proper operation.

VI. PRECAUTIONS

- To assure that operation will be trouble-free, attention should be given to the following points:

- ALWAYS TEST THE IC-2A EACH TIME BEFORE ATTACHING TO A PATIENT.

- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.

- Gas supplies must be maintained at 50 ±5 psi (345 ±34.5 kPa).

- Flow restrictions (e.g., flowmeter, check valves, etc.) must not be placed in supply lines.

- Gas going to patient should not be super-saturated, as evidenced by excessive rain-out in the tubing. Condensation droplets on the inner walls of the tubing is normal.

- Humidifier, when used, must be placed between PATIENT connection on IC-2A and hose in patient circuit. DO NOT PLACE IN SUPPLY LINE.

- When setting INSP. TIME and EXP. TIME controls, for optimum repeatability, always approach setting by turning knob in a counterclockwise direction.

- Humidifier should have low compliance, and water maintained at a high level to minimize compliance changes.

- Expiration Valve must be positioned with diaphragm cap (white section with pilot hose connection) up. Exhaust port, on bottom, should be unimpeded. (White adapter section on exhaust port of the exhalation valve may be removed to limit the amount of noise produced due to resonance. Do not connect any devices such as spirometer, alarms, monitors, etc. to exhalation valve line).

- WHEN THE VENTILATOR MUST BE USED UNATTENDED, ALWAYS USE WITH AN ALARM SYSTEM, SUCH AS THE BIO-MED DEVICES M-10 OR M-1. PRESSURE ALARMS SHOULD BE T-CONNECTED TO HOSE ATTACHED TO GAUGE FITTING OF IC-2A.

- When setting controls, always start with PEEP/CPAP control fully clockwise, and MAX PRESSURE control fully counterclockwise to avoid setting PEEP/CPAP above the maximum pressure limit.

- Never force the needle valve controls. (INSP. TIME, EXP. TIME, PEEP/CPAP and MAX. PRESSURE). When they are seated (fully clockwise) they must be firm, but not over-tightened.

- Should the INSP. TIME, EXP. TIME, or FLOW RATE control knobs come loose for any reason, do not attempt to re-fasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, ventilator must be

returned to BMD for recalibration.

- When the Ventilator is used at altitudes significantly above sea level, or in non-pressurized aircraft, the calibration of INSP. TIME and EXP. TIME must be corrected. The actual times will be greater than the panel marking by approximately 2 ½% for every 1000' of altitude.

- The pressure levels set by the MAX. PRESSURE and PEEP/CPAP controls are somewhat affected by the flow rate. These controls should be set with the flow rate used. If flow rate is changed, the MAX. PRESSURE and PEEP/CPAP levels should be checked.

- When a compressor is used as the power source, steps should be taken to filter and dehumidify the room air before introducing it into the IC-2A.

- Do not lean on or place excessive weight on the IC-2A while it is mounted on a bracket since the bracket is designed to support only the IC-2A.

- Moisture or dirt in the IC-2A will cause it to function improperly.

- It is recommended that the BMD patient circuit #8002A be used with the IC-2A. The use of other valves may cause the attainable upper level of PEEP and maximum pressure to change. If necessary, the unit may be recalibrated for available exhalation valves.

- Always turn on the IC-2A before attaching to the patient, to avoid erroneous breaths.

- Whenever the IC-2A is turned off, disconnect the patient before turning the ventilator back on, in order to avoid erroneous breaths.

VII. MAINTENANCE

A. NORMAL CARE

The IC-2A Ventilator requires very little maintenance. It should be protected from abusive mechanical shock and kept in a clean condition.

The IC-2A should only be cleaned by wiping the outside surfaces with alcohol applied to a tissue or cloth. It should never be sprayed with or immersed in any other liquid.

The instrument should be returned to BMD for repair.

The patient circuit supplied, BMD part #8002A is disposable and should be replaced for every patient, or during extended periods for a single patient. It is recommended that the patient circuit be changed at least every 24 hours.

Care should be taken in connecting supply hoses to the POWER OXYGEN and AIR fittings. Hand tightening of these fittings is sufficient. Do not over-tighten with a wrench, as the fittings could be damaged. Never connect a water supply to these fittings. Only clean, dry, oil-free medical grade gas may be used.

B. CHECKOUT PROCEDURE

For the following tests, the unit will require supply connections of 50 ±5 PSI (345 ±34.5 kPa) medical grade oxygen, an adult patient circuit (Bio-Med #8002A) and a test lung (Bio-Med #1020).

Unless otherwise stated, all controls and switches are set as follows:

Connect 100% 02 supply at 50 PSI (345 kPa) to LOGIC GAS SUPPLY
Connect 100% 02 supply at 50 PSI (345 kPa) to PATIENT GAS SUPPLY
CYCLE/MANUAL CPAP to CYCLE
INSPIRATORY TIME to 1 sec
EXPIRATORY TIME to 2 sec
FLOW RATE to 30 LPM
MAXIMUM PRESSURE fully CCW
PEEP PRESSURE fully CW
NORMAL/SIMV to NORMAL
INSPIRATORY EFFORT fully CW
ON/OFF valve to OFF
Attach patient circuit - patient end occluded

NOTE: Read through each numbered procedure thoroughly before proceeding with that check. Before starting each check, return unit to above settings.

1. LOGIC SUPPLY INTEGRITY

Turn patient gas supply off. Place your ear near the back of case. There should be no indication of internal leak.

2. PILOT VALVE BLEED

With both supplies on, place your ear near back of case. An audible internal leak is normal.

3. PILOT VALVE SEAL

With both supplies pressurized and ON/OFF valve to OFF, occlude the circuit exhalation valve exhaust port and observe the manometer on the unit. There should be no continuous rise in pressure indicated by manometer.

4. MANOMETER

Using a variable low-pressure source and known standard, verify 3% full-scale accuracy and a zero of +/- 1 cm.

5. RELIEF VALVE

CAUTION: Proceed with care. If the relief valve is malfunctioning, damage to the manometer may occur during this check.

NOTE: The point at which the relief valve begins to fully open may cause oscillation in the manometer. This is normal.

Set Flow Rate to minimum flow. Set ON/OFF switch to ON. Occlude circuit exhalation valve exhaust port and observe manometer. Slowly increase the flow rate to 20 LPM. A minimum of 100 cm of pressure should be indicated during inspiratory. Continue to slowly increase flow to 75 LPM. The pressure during inspiratory should not be less than 100 cm or greater than 130 cm.

6. MAXIMUM PRESSURE

Set INSPIRATORY TIME to 2 sec. Set ON/OFF switch to ON. Observe the manometer while increasing the flow rate through its entire range. The circuit pressure during inspiratory must be 100 cm or greater through entire flow range.

7. MAXIMUM PRESSURE ZERO

Turn Maximum Pressure knob fully CW. Set ON/OFF switch to ON. Observe the manometer. Except at start of inspiratory, no more than 1 cm rise in pressure should be observed.

8. FAILSAFE

Set ON/OFF switch to ON. Manometer should indicate Maximum Pressure during Inspiratory. Slowly decrease the logic supply pressure. At a supply pressure of 30 PSI or less, the patient circuit should stop pressurizing while the unit continues to cycle.

9. PEEP PRESSURE

Turn PEEP knob fully CCW and install test lung at patient end of circuit. Set ON/OFF switch to ON. The test lung should fill by the second breath and the manometer should indicate a PEEP pressure of 25 cm ±3. Switch CYCLE/MANUAL CPAP switch to MANUAL CPAP. Unit will continue cycling without inspiratory pressurization and with no CYCLE INDICATOR action. PEEP pressure should be 25 cm ±3. Press and release the Manual Button. A pressurized bolus of gas will be delivered.

10. PEEP ZERO

Set ON/OFF switch to ON. Observe manometer. No pressure should be indicated during the expiratory phase.

11. INSPIRATORY EFFORT

Remove occlusion from patient end of circuit. Set ON/OFF switch to ON. With 15 ±5 cm of negative pressure applied to the patient circuit, the DEMAND INDICATOR should activate and the unit should trigger (initiate a breath). Turn the INSPIRATORY EFFORT knob CCW until the unit auto-cycles (demand triggers at the end of every inspiratory phase). Slowly turn the knob back CW until the unit stops auto-cycling. A demand of 0.5 cm of negative pressure applied to the patient circuit should trigger a pressurized breath.

Install the test lung on patient circuit. Turn the PEEP knob fully CCW. Turn the INSPIRATORY EFFORT fully CCW. If the unit does not auto-cycle at this point, slowly decrease the PEEP pressure until the unit does auto-cycle. This must occur before the PEEP pressure has been reduced to less than 20 cm.

12. INSPIRATORY TIMES

Attach the patient end of the patient circuit to a test instrument used for measuring inspiratory time. Set ON/OFF valve to ON. While turning the INSPIRATORY TIME knob in a CCW direction, verify that all indicated times are within ±10% of panel values.

13. EXPIRATORY TIMES

Set up as in #12. While turning the EXPIRATORY TIME knob in a CCW direction, verify that all indicated times are within ± 10% of panel values. While the unit is in inspiratory, move the EXPIRATORY TIME knob CW to the full IMV position, against the stop. For an accurate reading of the back-up timer it is important that the expiratory knob be positioned against the stop before the end of the inspiratory phase. The back-up timer should trigger the unit into inspiratory, indicating an expiratory time between 9.0 and 12.0 sec. As the unit continues to be cycled by the back-up timer, the expiratory times should not decrease to less than 9.0 seconds.

14. MAXIMUM IMV TIME

Set up as in #12. Set EXPIRATORY TIME knob against the stop in the IMV range. Set NORMAL/SIMV to SIMV. Set ON/OFF switch to ON. Turn the INSPIRATORY EFFORT knob CCW until the unit auto-cycles. Using a stopwatch, measure the time between observed pressurized breaths. This time should be between 45-150 sec.

15. FLOW RATES

Attach the patient end of the patient circuit to a test instrument used for measuring flow. Set ON/OFF valve to ON. Verify that indicated flow rates are within ±10% of panel values. Turn FLOW RATE knob in a CCW direction.

C. CALIBRATION

The accuracy of the instrument's indicators and controls should be retained over its life as long as it has not been subject to abuse. The calibration of the pressure gauge, flow control, and timing controls may be checked with relative ease.

Note:
The calibration of the two timing controls (INSP. TIME and EXP. TIME) and the flow rate control depends on the fixed position of the knobs on their shafts. Should these knobs come loose, do not attempt to refasten. Return the instrument to Bio-Med Devices for repair.

The pressure gauge readings can be compared to a standard by teeing into the hose connected to the GAUGE fitting of the IC-2A, and connecting it to the standard gauge.

Should the gauge need zeroing, this may be accomplished while the instrument is inoperative by removing the gauge's lens and setting the zero screw adjust on the front dial of the gauge. If the calibration of any of the indicators or controls is in error, then the instrument should be returned to BMD for adjustment.

D. IF SERVICE IS REQUIRED

The IC-2A Ventilator should be returned to BMD, for any repair or service that may be required.

Maintenance scheduling of the Bio-Med Devices' IC-2A Pneumatic Ventilator is dependent upon frequency of use, condition of supply gases, and handling. It is recommended that units operated on a regular basis be factory serviced annually. For units used infrequently, a maximum of 3 years between factory service is recommended. Qualified personnel following prescribed checkout procedures may periodically verify calibration. The annual service procedure should be performed by experienced personnel at the factory. Field service beyond minor adjustment is not recommended due to the IC-2A's unique pneumatic logic circuit.

PACK THE INSTRUMENT SO THAT IT'S METERS, CONTROL KNOBS, AND CONNECTIONS ARE ADEQUATELY PROTECTED. Ship pre-paid to:

BIO-MED DEVICES INC.
61 SOUNDVIEW ROAD
GUILFORD, CT 06437

TABLE I

RATE & I/E RATIO

		INSPIRATORY TIME (SEC.)					
		.40	**.50**	**.75**	**1.00**	**1.50**	**2.00**
EXPIRATORY TIME (SEC.)	**.50**	67 1:1.3	60 1:1	48 1.5:1	40 2:1	30 3:1	24 4:1
	.60	60 1:1.5	55 1:1.2	44 1.3:1	38 1.7:1	29 2.5:1	23 3.3:1
	.75	52 1:1.9	48 1:1.5	40 1:1	34 1.3:1	27 2:1	22 2.7:1
	1.00	43 1:2.5	40 1:2	34 1:1.3	30 1:1	24 1.5:1	20 2:1
	1.50	32 1:3.8	30 1:3	27 1:2	24 1:1.5	20 1:1	17 1.3:1
	2.00	25 1:5	24 1:4	22 1:2.7	20 1:2	17 1:1.3	15 1:1
	4.00	14 1:10	13 1:8	13 1:5.3	12 1:4	11 1:2.7	10 1:2

$$\text{RESPIRATORY RATE} = \frac{60}{(\text{INSP. TIME} + \text{EXP. TIME})}$$

$$R = \frac{60}{(T_I + T_E)}$$

TABLE II

TIDAL VOLUME

		INSPIRATORY TIME (SEC.)					
		.40	**.50**	**.75**	**1.00**	**1.50**	**2.00**
FLOW RATE (LPM)	**20**	130	170	250	330	500	670
	30	200	250	375	500	750	1000
	40	270	330	500	670	1000	1330
	50	330	420	630	830	1250	1670
	60	400	500	750	1000	1500	2000
	70	470	580	875	1170	1750	2330
	75	500	630	940	1250	1880	2500

TIDAL VOLUME (ml.) = INSP. TIME X FLOW RATE (ml/sec.)

$V_T = T_I \times V_I$

APPENDIX A

EUROPEAN AGENT

Bio-Med Devices' Official Agent in Europe is:

HORST HÖRNLA

H + H Intermed
Schwedenstraße 32
87463 Dietmannsried-Reicholzried
United Germany

Telefon: (08 31) 6 31 86
Fax: (08 31) 6 09 54

APPENDIX B

MRI TEST

The Bio-Med Devices IC-2A MRI ventilator was tested approximately 2 ½ feet inside the bore of a 1.5 tesla MRI unit at which point the magnetic field was estimated to be 13,000 gauss.

The results of the test were as follows:

1. There was no detectable magnetic attraction of the ventilator.
2. The operation of the ventilator was not affected.
3. There was no effect on the MRI image.

Although this test was performed within the bore of the MRI unit, Bio-Med Devices does not recommend the ventilator be placed inside the bore in practice. Minimum proximity of one meter should be observed.